

### **REMARKS**

In response to the Office Action mailed October 5, 2010, Applicants have amended claims 1 and 3-10 to clarify particular aspects of the present invention. Claim 2 has been cancelled and no new claims have been added. It is urged that support for all the claim amendments may be found throughout the as-filed specification and original claims, for example, on page 6, lines 16-22; page 9, lines 20-24; page 10, line 30 to page 11, line 18; page 29, lines 14-20; Figures 1-5, and claim 2. No new matter has been added. The above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made solely to clarify particular aspects of the presently claimed invention, without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Following the amendments, claims 1-10 are pending and under examination. Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

### **SPECIFICATION**

The Examiner states that the lengthy specification has not been checked to the extent necessary to determine the presence of all minor errors. Further, the Examiner requests Applicants' cooperation in correcting any error of which Applicants may become aware of in the specification. Applicants submit that they have not become aware of any errors in the specification that require correction. Applicants kindly ask the Examiner to point out any errors in the specification that require correction.

### **CLAIM REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, ENABLEMENT**

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Specifically, the Examiner alleges that the specification, while being enabling for binding a component in a sample to magnetic microparticles when the sample is in contact with the magnetic microparticles, allegedly does not reasonably provide enablement for binding any

components in a sample to the magnetic microparticles when the sample is never placed in contact with the microparticles.

Applicants thank the Examiner for pointing out what appear to be some inconsistencies in the present claims. Accordingly, Applicants have amended to claims to attend to this and other grounds of rejection. Applicants respectfully submit that the as-filed specification fully enables the instant claims and that one having skill in the art would not require any undue experimentation to practice the entire scope of the presently claimed invention.

Applicants, without acquiescence, have amended claim 1 to recite the steps of:

(a) providing a vessel (26), wherein the vessel contains microparticles (22) in a solution (23), wherein the solution comprises a sample, wherein the sample comprises a desired biological component, wherein the desired component is a biomolecule selected from the group consisting of: a nucleic acid, a protein, a peptide, a cell organelle, a bacterium, a cell, and a virus;

(b) incubating the microparticles and the sample in the vessel for a time sufficient for the microparticles to bind the desired component from the sample;

Accordingly, Applicants submit that the claims are fully enabled by the as filed specification because claim 1 recites binding a component in a sample to magnetic microparticles when the sample is in contact with the magnetic microparticles, which the Examiner has acknowledged is enabled by the as-filed specification.

Reconsideration and withdrawal of this basis for rejection is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, FIRST REJECTION

Claims 1-10 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicants respectfully traverse this basis for rejection and submit that the instant claims are both clear and definite and that one having ordinary skill in the art would readily understand the metes and bounds of the presently claimed invention.

The Action alleges that the claims are generally narrative and indefinite, failing to conform with current U.S. practice. The Action further alleges that the claims appear to be a literal translation of a foreign document into English and that the claims are replete with grammatical and idiomatic errors.

Applicants respectfully submit that they were of the opinion that this issue was raised and addressed in the Office Action mailed May 5, 2010 (see pages 4-5) and Applicants response of August 4, 2010. Thus, Applicants submit that this basis of rejection has been obviated by the previous response and claim amendments. Hopefully, the further amendments noted above have succeeded in removing any remaining issues in this regard. Accordingly, Applicants respectfully request that the Examiner should particularly point to the alleged errors so that Applicants may further address any remaining basis of rejection. Reconsideration and withdrawal of this basis for rejection is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, SECOND REJECTION

Claims 1-10 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being incomplete for omitting essential steps, such omission amounting to a gap between the steps.

Applicants respectfully traverse this basis for rejection and submit that the instant claims are both clear and definite and that one having ordinary skill in the art would readily understand the metes and bounds of the presently claimed invention.

The Examiner alleges that the omitted steps are: at least providing a vessel and placing magnetic microparticles in the vessel and placing a sample including a desired component in the vessel in contact with the microparticles. Applicants submit that the claims have been amended, without acquiescence, to recite a method for handling microparticles comprising providing a vessel providing that contains microparticles in a solution, wherein the solution comprises a sample, wherein the sample comprises a desired biological component, and incubating the microparticles and the sample in the vessel for a time sufficient for the microparticles to bind the desired component from the sample. Accordingly, Applicants submit that claims 1-10 are not incomplete for omitting essential steps.

The Examiner further alleges a number of clarity issues, which Applicants address in the order presented in the outstanding Office Action.

1. The Examiner alleges that it is unclear how one change of solutions and one mixing is related to binding a sample component, that the claims as drafted are ambiguous and unclear, and that the claims do not clearly define the steps or order in which the steps are performed. Applicants respectfully disagree. Applicants respectfully submit that one having ordinary skill in the art would appreciate that changing solutions and mixing microparticles in solution results in more specific binding of the desired component to the microparticle, optimization of binding of the desired component to the microparticle through manipulation of salts concentration, pH, etc. and often less undesired components bound to the microparticles. Moreover, Applicants submit that the order of steps is clearly defined and that one having ordinary skill in the art would recognize that the method steps are not ambiguous, but instead allow for various combinations of changing solutions, e.g., washing microparticles, mixing solutions, binding microparticles to magnetic tools, and transfer of magnetic particles to another vessel. The skilled artisan would further appreciate that such combinations would vary depending on the desired component, the sample, and the type of magnetic particles selected for use in the presently claimed methods.

2. The Examiner also alleges that it is unclear how the claims can exclude moving the microparticles to another vessel, when no prior location has been established for the microparticles. Applicants respectfully submit that this basis of rejection has been obviated because the claims have been amended to recite that the microparticles are located in a vessel. Thus, claim 1 requires that at least one change of solutions and one mixing occur in the same vessel.

3. The Examiner further alleges that the relationship of “one change of solutions” to binding components of a sample is unclear. Applicants have responded to this basis of rejection in point 1 above.

4. The Examiner also contends that the relationship of the sample and solutions is unclear. Applicants respectfully disagree. Applicants respectfully submit that claim 1 recites that the solution comprises a sample. After the solution and the microparticles are incubated for

a sufficient period of time to allow the microparticles to bind to the desired component, the initial solution may be removed, thereby removing some of the sample not containing the desired component bound to the microparticles. Applicants respectfully submit that one having skill in the art would appreciate the relationship of the claims sample and solution.

4(b). The Examiner alleges that it is not clear where the sample and solutions are located. Applicants respectfully disagree and submit that the claims clearly recite that the samples and solutions are located in the vessel.

4(c). The Examiner further alleges that the phrase “change of solutions” is unclear. Applicants respectfully disagree and submit that the claims have been amended to recite wherein each change of solutions involves removal of one solution from the vessel and adding another solution into the vessel. The skilled artisan would appreciate that the solutions may be the same or different depending on, for example, the particular desired component, the sample, and the type of microparticle used in the method.

5. The Examiner additionally alleges that the phrase “one mixing” is unclear. Applicants respectfully disagree. Applicants respectfully submit that mixing is not specially defined in the application and thus, given its ordinary and customary meaning. Applicants further submit that the claims recite that the microparticles are mixed in the solution in the vessel by moving the magnet of magnetic tool and thereby mixing the microparticles in the solution. The skilled artisan would readily appreciate that the microparticles would be mixed with any the other components in the solution in the vessel. The skilled artisan would further appreciate that mixing could, for example, facilitate binding of the desired component to the microparticles or reduce binding of undesired components to microparticles, depending on the nature of the sample.

6. The Examiner alleges that the “wherein” clauses in claim 1 that are directed to the desired sample component is not further limiting of the method and that the sample and components thereof are not required for the method. Applicants respectfully disagree. Applicants, without acquiescence have amended claim 1 to recite a method for handling microparticles comprising providing a vessel providing that contains microparticles in a solution, wherein the solution comprises a sample, wherein the sample comprises a desired biological

component, and incubating the microparticles and the sample in the vessel for a time sufficient for the microparticles to bind the desired component from the sample. Thus, Applicants respectfully submit that one having ordinary skill in the art would appreciate that the presently claimed methods recite a sample and components; thus, they further limit a claim not reciting these elements. Moreover, by virtue of being claimed, the sample and components are required elements in the presently claimed method.

7. The Examiner also alleges that it is unclear whether each of the claims dependent upon claim 1 are intended to add further steps or are an attempt to further define the steps of claim 1. Applicants respectfully disagree. Applicants respectfully note that the dependent claims add further steps and/or further define the steps of claim 1. Applicants respectfully request that the Examiner more particularly point out which dependent claims are unclear and that particular reason that they are unclear.

8. The Examiner alleges that claim 2 it is unclear if step (a) is meant to be an additional step to that of claim 1. Further, the Examiner alleges that steps (b) and (c) do not clearly recite when and where the steps occur relative to the steps of claim 1. Applicants respectfully submit that claim 2 has been canceled; thus, this basis of rejection is moot. However, Applicants respectfully submit that with regard to all other claims reciting solution/solutions, it is clear that the vessel comprising “a” or “the” solution is one in which there is but solution. In addition, the skilled artisan would recognize that removing one solution and adding another solution to the vessel necessarily involves two solutions (the removed solution and the added solution) in the vessel and that exchanging the solution in the vessel for another solution requires two solutions. Thus, Applicants respectfully submit that the use of solution and solutions in the presently claimed method is clear.

9. In regard to claim 3, the Examiner As to claim 3, it is unclear what is meant by “homogenized from the inner surface of the vessel.” Applicants respectfully submit that claims 3 and 7 recite binding microparticles to the inner surface of the vessel using an external magnet. Applicants note that once bound to the inner surface the solution is no longer homogenous, that is, the mass of microparticles has been localized to the inner surface of the vessel and the remaining solution in the vessel has been substantially cleared of microparticles. Accordingly,

homogenizing the microparticles from the inner surface to the solution refers to making the solution/microparticle milieu a more homogenous composition. Applicants respectfully submit that one having ordinary skill in the art would appreciate this concept. Moreover, the step of homogenizing the microparticles from the inner surface of the vessel occurs after the microparticles have been bound to the inner surface of the vessel; but, the homogenizing step can also precede or follow other steps such as changing solutions or mixing the microparticles.

In addition, the Examiner alleges that claim 3(c) contradicts claim 1 because claim 1 excludes moving the microparticles to another vessel, whereas claim 3(c) states the method involves moving the microparticles to another vessel. Applicants respectfully disagree. Present claim 1 recites that at least one change of solutions and at least one mixing must take place in the same vessel. However, claim 1 does not exclude additional steps, changes of solution, mixing, and transfer, which can involve moving the microparticles to another vessel.

10. The Examiner also alleges that claims 3-4 and 7 lack sufficient antecedent basis for the phrase “inner surface of the vessel.” Applicants respectfully disagree and note that the inner surface of the vessel is an inherent component of the vessel and thus, one having skill in the art would appreciate the metes and bounds of this phrase. Applicants further note that inherent components of elements recited have antecedent basis in the recitation of the components themselves. For example, the limitation “the outer surface of said sphere” would not require an antecedent recitation that the sphere has an outer surface. *See Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1359, 61 USPQ2d 1216, 1218-19 (Fed. Cir 2001); see also M.P.E.P. § 2173.05(e).

11. The Examiner further alleges that claim 4 is indefinite because it is unclear how the claim further limits the method of claim 1; what constitutes a whole procedure; the relationship of the washing solutions to the previously recited solutions of claim 1; and how solutions can be changed in or in separate vessels. Applicants respectfully submit that claim 4 has been amended and that this basis of rejection is now moot.

12. The Examiner also alleges that claim 5 is indefinite because it lacks sufficient antecedent basis for the “solution”; because the difference between the three different recitations of “solution” is unclear; and because it is unclear how, when, and where the stretching and

releasing occur relative to the steps of the method. Applicants respectfully submit that claim 5 has been amended and that this basis of rejection is now moot.

13. The Examiner also alleges that claim 1 broadly references mixing but does not state what is mixed or when and how the mixing is performed and thus, it is unclear how claim 6 relates to claim 1. Applicants respectfully submit that claims 1 and 6 have been amended and that this basis of rejection is now moot.

14. The Examiner indicates that the previous indefinite rejections applied to claims 3 and 5 are also applicable to claim 7. Applicants respectfully submit that the response to the rejections based on points 9 and 10 above, are equally applicable to this basis of rejection and are therefore reiterated by reference here. With regard to the rejections based upon claim 5, Applicants submit that claim 7 has been amended and that this basis of rejection is now moot with regard to claim 7.

15. The Examiner also alleges that claims 8-10 are indefinite because the relationship between the term "a solution" of claim 8 and the solutions of claim 1 are unclear. In addition, the Examiner contends that it is unclear at what point the collection and further references to events in claim 8-10 occur relative to the steps of claim 1. Applicants respectfully submit that claims 8-10 recite "the solution"; thus, the relationship between the solution of claims 8-10 relative to the solution of claim 1 is clear. Applicants further submit that one having ordinary skill in the art would appreciate that the collecting steps and subsequent steps of any of claims 8-10 could precede and/or follow at least one change of solutions and/or at least one mixing of the microparticles.

16. The Examiner also alleges that claim 9 is a combination of previous recitations which have been addressed and that Applicant should take note of the Examiner's prior rejections. Applicants respectfully submit that claim 9 has been amended and that this basis of rejection is now moot.

17. The Examiner also alleges that claim 10 is indefinite because it is unclear how the claim further limits the method of claim 1 and because it is unclear if the filter is located in or on an exterior bottom of the vessel. Applicants respectfully submit that claim 10 has been substantially amended such that it would be clear to one having ordinary skill in the art how



claim 10 further limits claim 1. In addition, Applicants submit that the as-filed specification clearly discloses embodiments wherein the filter is inside the vessel, on the bottom of the vessel, see, *e.g.* Figure 13-22 and 26-32.

Applicants respectfully submit that the present claims are both clear and defined and that one having ordinary skill in the art would recognize the metes and bounds of the presently claimed invention.

Accordingly, Applicants respectfully request that the Examiner carefully reconsider and withdraw these bases for rejection.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102, FIRST REJECTION

Claims 1-10 stand rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by Korpela (WO96/26011). As an initial note, Applicants respectfully point out that the Action has incorrectly identified WO96/26011 as “Korpela.” Applicants respectfully submit that Siddiqi is the sole inventor and Applicant of WO96/26011. Accordingly, Applicants hereinafter refer to WO96/26011 as the ‘011 publication.

The Examiner alleges that the ‘011 publication discloses an apparatus and a method for treating magnetic particles (see abstract and page 13, line 17- line 20); wherein mixing, separation and cleaning of the particles take place in a container without moving the particles out of said container (see esp. figures 5a-f, page 18, line 27- page 19, line 21, page 8, line 17- line 20 and page 21, line 29- line 32); wherein the device employs magnetic tool (4, 30) that stretches the elastic membrane (2’) into the container; wherein the magnetic tool attracts the microparticles when inserted in the container; and wherein the tool can also includes a sleeve (page 18, line 23).

Applicants respectfully traverse this basis for rejection and submit that the ‘011 publication fails to anticipate the presently claimed invention because they do not teach each and every element of the claims. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants respectfully submit that the '011 publication fails to teach a magnetic tool equipped with a protective shield (21) or coating and that comprises a ferromagnetic sleeve. In contrast, the '011 publication discloses an apparatus with an external magnet that never comes into contact with the microparticles; and thus, is clearly distinguished from the presently claimed invention.

Accordingly, for at least these reasons, the '011 publication fails to anticipate the presently claimed invention because they do not teach each and every element of the claims. Reconsideration and withdrawal of this basis for rejection are respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102, SECOND REJECTION

Claims 1-2 stand rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by Siddiqi (US2006/0207944; hereinafter referred to as "the '944 publication"). Specifically, the Examiner alleges that the '944 publication teaches each and every element of the presently claimed invention.

Applicants respectfully traverse this basis for rejection and submit that the '944 publication fails to anticipate the presently claimed invention because they do not teach each and every element of the claims. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants respectfully submit that the disclosure of the '944 publication is substantially the same as the '011 publication. Similarly, Applicants respectfully submit that the '944 publication fails to teach a magnetic tool equipped with a protective shield (21) or coating and that comprises a ferromagnetic sleeve. In contrast, the '944 publication discloses an apparatus with an external magnet that never comes into contact with the microparticles; and thus, is clearly distinguished from the presently claimed invention.

Accordingly, for at least these reasons, the '944 publication fails to anticipate the presently claimed invention because they do not teach each and every element of the claims. Reconsideration and withdrawal of this basis for rejection are respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102, THIRD REJECTION

Claims 1-2 stand rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by Gordon (US2004/0047765; hereinafter referred to as “the ‘765 publication”). Specifically, the Examiner alleges that the ‘765 publication discloses a process for separation and purification via processing under influence of a magnetic field that includes each and every element of the claimed invention.

Applicants respectfully traverse this basis for rejection and submit that the ‘765 publication fails to anticipate the presently claimed invention because they do not teach each and every element of the claims. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants respectfully submit that the ‘765 publication fails to teach a magnetic tool equipped with a protective shield (21) or coating and that comprises a ferromagnetic sleeve. Thus, in contrast to the Examiner’s assertions, the ‘765 publication does not teach each and every element of the present claimed methods.

Reconsideration and withdrawal of this basis for rejection are respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102, FOURTH REJECTION

Claims 1-10 stand rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by Korpola (US Patent No. 6,468,810; hereinafter referred to as “the ‘810 patent”). Specifically, the Examiner alleges that the ‘810 patent discloses a device and method for purifying liquids that includes mixing, washing, and changing liquids that includes all elements of the presently claimed invention.

Applicants respectfully traverse this basis for rejection and submit that the ‘810 patent fails to anticipate the presently claimed invention because they do not teach each and every element of the claims. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”

*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The Examiner alleges that the '810 patent discloses that magnets of the device for transfer have sleeves and a common membrane (column 8, lines 7-9). Applicants respectfully submit that the presently claimed invention, recites a magnetic tool comprising a ferromagnetic sleeve, which is a feature of the magnetic device that is not disclosed in the '810 patent.

The Examiner further alleges that the '810 patent discloses that microparticles can be transferred to the wash liquid in well 62 even directly from a separate storage vessel and that in differing methods for processing of samples various proceedings according to each method may be realized in the wells of plate 56, such as stages for heating, cooling, mixing, measuring (analytical methods) and dosage of reagents. However, in contrast to the claimed methods, the methods of the '810 patent disclose that the particles are transferred to successive wells to accomplish different treatment steps, *see, e.g.*, column 11 line 64 to column 12, line 4. Thus, Applicants submit that the '810 patent fails to disclose a method for handling microparticles that bind a desired component from a sample comprising at least one mixing step and one change of solutions in the same vessel (*e.g.*, well).

Thus, in contrast to the Examiner's assertions, the '810 patent does not teach each and every element of the present claimed methods. Reconsideration and withdrawal of this basis for rejection are respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be allowable.  
Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,  
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